

- 1           76. (Amended) The apparatus of claim 75, wherein the microprocessor calculates the  
2   10th percentile value of the data set and identifies the characteristic [**abnormality**] **abnormal**  
3   **pattern or distribution** based on the 10th percentile value.

## REMARKS

### I.    **STATUS OF THE CLAIMS**

Claims 39-80 are pending in the application, of which claims 50, 51, 58, 63-67, 74, and 77-80 are withdrawn from consideration as being drawn to non-elected invention.

Claims 39-49, 52-57, 59-61, 69-73, and 75-76 were rejected under the judicially created doctrine of obviousness-type double patenting.

Claim 70 (subject matter herein incorporated into claim 69) has been cancelled without prejudice.

Claims 39 and 69 are independent claims, presently under examination.

Claims 39, 62, and 68 stand rejected under 35 U.S.C. § 102.

Claims 69-71 stand rejected under 35 U.S.C. § 103.

Claims 70 (subject matter herein incorporated into the preamble of claim 69) was rejected under 35 U.S.C. § 112(2). This cancellation was not made for the purpose of narrowing the scope of the claims.

Claims 40-61 and 72-76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and pending resolution of the double patenting rejection.

### II.   **TERMINAL DISCLAIMER**

A terminal disclaimer in compliance with 37 CFR § 1.321(c) has been filed, attached herein, to overcome the obviousness-type double patenting rejection of the pending claims.

### III. AMENDMENTS

The claims 39, 41, 43, 47, 52, 55, 61, 68, 69, and 71-76 have been amended. It is believed that the claims do not involve the addition of any new matter. A clean copy of the amended Claims are provided in Appendix A *infra*.

### IV. AMENDED CLAIMS 39, 62, AND 68 ARE NOT ANTICIPATED UNDER 35 U.S.C. § 102(b) BY HOJAIBAN (US 4,018,219); AND CLAIMS 69 AND 71 ARE PATENTABLE UNDER 35 U.S.C. § 103 OVER HOJAIBAN BASED ON SUBSTITUTION BECAUSE THE APPLIED PRIOR ART AS A WHOLE FAILS TO SUGGEST THE APPLICANTS' INVENTION.

Claims 39, 62, 68 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hojaiban U.S. Patent No. 4,018,219 (hereinafter "Hojaiban"); and claims 69 71 were rejected under 35 U.S.C. § 103 over Hojaiban based on mere substitution. In particular, the Office Action states:

Claims 39, 62 and 68 are rejected under 35 U.S.C. 102(b) as being anticipated by Hojaiban (US 4018219). Hojaiban discloses a method and apparatus for detecting illness based on an abnormality in the heart rate variability. The short-term heart rate variability is determined by comparing the elapsed time between each heartbeat and the previous one (c 2, 11 6-12), read to be the commonly used RR interval. The heart beat variability measurements from a newborn infant can be used to alert the caregivers to symptoms of an illness (c 1, 11 14-24).

(See Office Action, par. 6, page 6)

The Office Action further states:

Claims 69-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hojaiban (US 4018219). As discussed in paragraph 6, Hojaiban discloses a method and apparatus using an abnormality in the heart rate variability, an increased variation in the RR interval, to alert caregivers to an illness in a newborn. Hojaiban uses a digital register (96), a buffer (98), a comparator (100), an up-down counter (102) and an accumulator (130) to identify the abnormality in the heart rate variability. Hojaiban discloses the claimed invention except for the abnormality in the heart rate variability being identified by a microcomputer. Substitution of a microcomputer in place of the register, the buffer, the comparator, the counter, and the accumulator to calculate the abnormality in the heart rate variability is viewed as an obvious design choice based on the mere substitution of a known functional equivalent. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and apparatus for detecting illness based on an abnormality in the

heart rate variability as taught by Hojaiban, with a microcomputer serving as a known functional equivalent for the register, the buffer, the comparator, the counter, and the accumulator. One having ordinary skill in the art would have been motivated to make such a modification in the method and apparatus for detecting illness to provide a more compact device with fewer components to minimize the cost of the apparatus and reduce the number of elements in the apparatus that need to be maintained.

(See Office Action, par. 7, pages 6-7)

Applicants respectfully traverse the rejection of claims 39, 62, 68 as being anticipated by Hojaiban; and submit that claims 69 and 71 would not have been obvious under 35 U.S.C. § 103 over Hojaiban based on mere substitution because the applied prior art fails to teach or suggest the following present invention method or apparatus for detecting illness as recited in amended base claims 39 and 69, which calls for:

- ...monitoring time series of RR intervals in the patient; and
- ...identifying at least one characteristic abnormal pattern or distribution.

In view of the differences of claim 39 and Hojaiban, Applicants respectfully urge that the rejections of 39, 62, and 68 be withdrawn.

Moreover, the Examiner's reliance on the substitution does not supply the deficiencies of the Hojaiban disclosure. Hence, it is the Applicants' position that the cited are as whole fails to teach or suggest the claimed invention with in the meaning of 35 U.S.C. § 103 and request that the rejection of claims 69 and 71 be withdrawn.

## V. CONCLUSION

For the foregoing reasons, Applicants respectfully submit that claims 39-69, and 71-76 are in condition for allowance, and a notice for allowance is solicited. Should questions arise during examination, the Examiner is welcome to contact the Applicants' attorney at the telephone listed below.

Please charge any excess fees due and credit any overpayment to Deposit Account No. 50-0423.

A clean copy of the amended Claims are provided in Appendix A *infra*.

Please change the attorney docket number to 00115-07.

Respectfully submitted,



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